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MAY 25 2007
Appl. No.: 10/804,938
Atty. Dkt. No.: 10031165-1

REMARKS

In view of the following remarks, the Examiner is requested to allow Claims 1, 3-15 and 20-21, the only claims pending and under examination in this application.

Formal Matters

Claims 1, 3, 4 and 5 have been amended. Support for these amendments can be found throughout the application as originally filed and in the following exemplary locations: page 20, paragraph, 0071, lines 11-13; and claim 2 as originally filed.

Paragraph 0020 on page 7 has been amended.

Paragraph 00210 on page 46 has been deleted.

As no new matter is added by way of these amendments, entry of the amendments by the Examiner is respectfully requested.

Specification

The Examiner indicated that the objection to the Petition for color drawings listed in the previous Office Action is maintained because Applicants have not amended the specification so that the paragraph in the Specification regarding color drawings is the first paragraph of the brief description of the drawings.

Applicants have amended paragraph 0020 and deleted paragraph 00210 so that the paragraph in the Specification regarding color drawings is the first paragraph of the brief description of the drawings. Applicants submit that the objection has been adequately addressed in light of the amendments to the Specification. As such, Applicants respectfully request withdrawal of the objection.

Claim Rejections - 35 USC § 112, second paragraph

Claims 2-6 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite based on the recitation of the terms "BTS" and/or "MMM" found in claims 2-5. The Examiner stated that these terms are acronyms, the meanings of which may change over time.

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Applicants have cancelled claim 2 and therefore the rejection of claim 2 is moot.

Applicants have amended claims 3-5, and in so doing have removed the references to "BTS" and "MMM." Based on these amendments, Applicants submit that this rejection is now moot and respectfully request its withdrawal.

Claim Rejections - 35 USC § 103(a)

Claims 1, 10-15, and 20-21 were rejected under 35 USC § 103(a) as allegedly being obvious over Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2nd ed., Cold Spring Harbor Laboratory Press, NY, pp. 7.12-7.15 and pp. 7.23-7.29 (1989) in view of Wang et al. (U.S. Patent No. 5,219,727) ('727).

In support of this rejection, the Examiner asserted that Sambrook et al. teach contacting an RNA isolation membrane column with an RNA-containing precipitate; namely performing chromatography on the RNA. The Examiner further asserted that the chromatography is performed in a column comprising a membrane; namely, a Dispocolumn comprising an oligo(dT) cellulose and a glass wool plug. According to the Examiner, the glass wool of Sambrook et al. is interpreted as a membrane because "wool" comprises a multi-fiber interwoven structure (i.e., a membrane) having spaces between the individual fibers (i.e., pores). In addition, the Examiner stated that because the column has oligo(dT) cellulose, the column is an RNA isolation column because polyadenylated (i.e., poly-A⁺) RNAs are isolated by the column.

Applicants have amended claim 1 to include the limitations of claim 2. Claim 2 was not rejected based on the above combination of references. Applicants take this as an acknowledgement by the Examiner that the combination of the Sambrook et al. and Wang et al. '727 references falls to render claim 2 obvious. Since the limitations of claim 2 have been incorporated into claim 1, Applicants submit that amended claim 1 is not obvious in light of the above combination. Claims 10-15 and 20-21 each depend ultimately from amended claim 1, and therefore those claims are

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not obvious by virtue of such dependency. As such, Applicants respectfully request withdrawal of the rejection.

Claims 2-6 were rejected as allegedly obvious over Sambrook et al. in view of Wang et al. '727, and further in view of Wang et al. (U.S. Patent No. 5,906,742) ('742) as evidenced by Pall Life Sciences (Bulletin #FAM-1050-C, Pall Corporation, Filterite Advanced Materials Division, San Diego, CA, 2002).

As indicated above, claim 2 has been cancelled and therefore the rejection as applied to claim 2 is moot. However, Applicants have amended claim 1 to incorporate the limitations of claim 2 and therefore applicants respectfully traverse this rejection as applied to claims 3-6 and as it may be applied to amended claim 1.

A factor in determining whether a *prima facie* case of obviousness has been established is whether there is a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In re Fine, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicants submit that there is no motivation or suggestion present in either the Sambrook et al. or Wang et al. '742 references, or in the knowledge generally available to one of ordinary skill in the art at the time the invention was made, to combine reference teachings in the manner proposed by the Examiner.

Claim 1, as amended, recites a membrane selected from the group consisting of polysulfone treated with hydroxypropylcellulose, PVDF (polyvinylidene fluoride), nylon, nitrocellulose, polysulfone, polysulfone and polyvinylpyrrolidone, PVP (polyvinylpyrrolidone), and composites thereof.

While the Examiner acknowledges that Sambrook et al. and Wang et al. '727 are silent with respect to MMM (polysulfone and polyvinylpyrrolidone) membranes. The Examiner indicates that this deficiency is made up by the addition of the teaching of Wang et al. '742. The Examiner states that Wang et al. '742 teach the

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use of solid phases in the form of asymmetric microfiltration membrane materials comprising PVP co-cast with polysulfone for filtering biological samples with the added advantage that the membranes are highly useful in the quick detection of components contained in liquid samples. According to the Examiner, it would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising a membrane as taught by Sambrook et al. and Wang et al. '727 with the membrane as taught by Wang et al. '742 with a reasonable expectation of success.

Sambrook et al. teach a Dispocolumn comprising a oligo(dT) cellulose and a glass wool plug. The Examiner interprets the glass wool plug to be a membrane, however, the glass wool plug is not a membrane as disclosed and claimed in the present application. It is clear from the specification and the application as a whole that the membranes of the present invention play a passive role and act as physical barriers to the RNA precipitate and retain the precipitate for purification. The glass wool of Sambrook et al. functions merely as a plug which allows for the loading of the column with oligo-(dT)-cellulose (pg 7.26, section 2). There is no indication or suggestion that the glass wool would be capable of effectively retaining RNA precipitate for purification. Rather, the glass wool provides a support for the packed oligo-(dT)-cellulose, and it is the oligo-(dT)-cellulose that plays a role in retaining the RNA.

Since the glass wool plug of Sambrook et al. does not function as a passive membrane which retains RNA precipitate for purification, there would have been no motivation to replace the wool plug with the asymmetric microfiltration membranes of Wang et al. '742 to arrive at the claimed invention.

The Examiner asserts that the ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in a method of preparing a cRNA sample substantially free of contaminants having the added advantage of allowing the quick detection of components contained in liquid samples.

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The column purification method of Sambrook et al. described on pages 7.26-7.29 is an affinity method of purifying poly(A)⁺ RNA from a preparation of total cytoplasmic RNA. Applicants respectfully submit that, contrary to the Examiner's assertion above, it is not clear that any benefit would be achieved by replacing the glass wool disclosed by Sambrook et al. with the membranes described by Wang et al. '742. The replacement of the glass wool of Sambrook with the membranes of Wang would not alter the mechanism by which the poly(A)⁺ RNA is separated and purified. The mechanism of separation and purification would still be based on the affinity binding of the poly(A)⁺ RNA to the oligo(dT)-cellulose by virtue of specific Watson-Crick base pairing. Since the separation mechanism of the Sambrook et al. oligo(dT)-cellulose column method is an active affinity mechanism, there would have been no motivation for the addition of passive polymeric membranes which would not have separated or retained the poly(A)⁺ RNA used in Sambrook et al. It's not at all clear that the proposed benefit of "allowing the quick detection of components contained in liquid samples" would manifest in the context of the method described by Sambrook et al. since the component of interest in that context is the poly(A)⁺ RNA which is separated and purified based on affinity binding and not on the basis retention by a passive membrane.

For the above reasons, there would have been no motivation to combine the cited references to arrive at the method of the claimed invention. As such, Applicants submit that a prima facie case of obviousness has not been established and respectfully request withdrawal of the rejection as applied to claims 3-6 and as it may be applied to claim 1.

Claims 7-9 were rejected as allegedly obvious over Sambrook et al. in view of Wang et al. '727 and further in view of Waggoner (U.S. Patent No. 5,627,027).

As previously discussed, Sambrook et al. fail to teach or suggest the limitations of claim 2, now incorporated into claim 1 as follows: "contacting a cRNA isolation column with the organic preparation of step (b), wherein said cRNA isolation column comprises a membrane selected from the group consisting of polysulfone treated with hydroxypropylcellulose, PVDF (polyvinylidene fluoride), nylon,

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nitrocellulose, polysulfone, polysulfone and polyvinylpyrrolidone, PVP (polyvinylpyrrolidone), and composites thereof."

Claims 7-9 each depend ultimately from claim 1 and contain the above elements by virtue of such dependency. Therefore, Sambrook et al. fail to disclose the above elements of claims 7-9.

The Examiner relies on Wang et al. '727 for their disclosure of cRNA and Waggoner for his disclosure regarding the labeling of nucleic acids with cyanine dyes. However, neither Wang et al. nor Waggoner teach or suggest the use of membranes selected from the group consisting of polysulfone treated with hydroxypropylcellulose, PVDF (polyvinylidene fluoride), nylon, nitrocellulose, polysulfone, polysulfone and polyvinylpyrrolidone, PVP (polyvinylpyrrolidone), and composites thereof. As such, the combined references fail to teach or suggest all of the elements of claims 7-9. For this reason, Applicants respectfully request withdrawal of the rejection.

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CONCLUSION

In view of the amendments and remarks above, the Applicant respectfully submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 327-3400.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. AGILENT 50-1078, order number 10031165-1.

Respectfully submitted,

Date: May 25, 2007

By: 

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